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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/960,706 | 09/24/2001 | William E. Munger | 044921-5029-01 | 4547 |
| 9629 .7590 02/28/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 | | | EXAMINER MORAN, MARJORIE A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 02/28/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/960,706 | | MUNGER ET AL. | |
| | Examiner | | Art Unit | |
| | Marjorie A. Moran | | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-65 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57, 70 and 71 is/are allowed.
- 6) ☒ Claim(s) 58-65 and 72-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/06 has been entered.

Claims 57-65 and 70-75 are pending. All rejections and objections not reiterated below are hereby withdrawn in view of the claim amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60, 62-65, 72, 73 and 75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These are NEW MATTER rejections.

A database comprising reference gene expression profiles, which is limited to be GenBank, as recited in amended claim 60, is new matter.

The original claims limited a computer system to be linked to GenBank, but did not limit any database to be one comprising a reference gene expression profile. New claim 70 limits the reference gene expression profile of the claimed computer system to be "part of" a database; which is interpreted to limit the database to comprise a reference gene expression profile. Page 15 of the originally filed specification discloses that databases for use with the inventive methods may be "designed" to include a gene expression database, and disclose that computer platforms and workstations may comprise the databases, thus which providing at least minimal support for a computer system interfacing with or comprising a database comprising a gene expression "profile." The originally filed specification also discloses several tables comprising statistical data for gene expression in normal vs. BPH samples, thus providing support for "databases" comprising a reference gene expression profile, as recited in new claim 70. However, Genbank does not comprise comparative gene expression values, nor any data specifically indicating differential expression of individual sequences in normal vs. BPH samples. For example, the NCBI record for accession number AA410383, which is the first sequence listed in instant Table 1, does not contain any information with regard to expression in prostate tissue at all.

In the response filed 11/13/06, applicant points to page 9 of the specification for support for the new limitations of claim 57, but does not point to support anywhere for a disclosure that Genbank is a database comprising a reference gene expression profile. As Genbank (interpreted to be the nucleotide portion of the NCBI database) is NOT a database comprising a reference gene expression profile, as now encompassed by the

combination of limitations recited in amended claim 60, claim 60 recites new matter, and is rejected.

An expression profile which comprises descriptive information for a subject, as recited in amended claims 62-65, is new matter.

The original claims limited a database to comprise descriptive information for a patient/subject. The originally filed specification, on pages 14-16, also discloses *databases* comprising descriptive information for a patient. The specification on page 15, lines 7-8, disclose that *databases* may also comprise gene expression information. Thus, the specification supports *databases* comprising both expression (profile) information and descriptive (patient/subject) information, as recited in the original claims. The Tables disclosed in the instant specification disclose differential expression levels for various nucleic acid sequences, but do not comprise descriptive information for individual patients or subjects. Nowhere do the originally filed specification or claims disclose or recite an expression profile which comprises descriptive information for a patient or subject. In the response filed 11/13/06, applicant does not point to support for new limitations, and none is apparent, as set forth above, therefore claims 62-65 recite new matter and are rejected.

An expression profile comprising statistical measures of differential expression of "20 or more" or "50 or more" nucleic acid sequences, as recited in new claims 72, 73 and 75, is new matter. Original claims 32 and 33 recited a computer system comprising

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a database containing information identifying expression levels of at least two genes in Tables 1-6, or Table 5, specifically. Original claims 40-42 recited a method wherein "at least two/five/ten" genes are compared. The original claims did not recite a database comprising "information" identifying expression levels of "20 or more" or "50 or more" nor any method of comparing at least 20 or 50 genes. The originally filed specification, on page 3 discloses that the expression levels "at least 2,3,4,5,6,7,8,9, 10 or more genes from any one of Tables 1-6" may be detected; pages 2-3 disclose screening a database comprising "two or more genes" from the Tables. The specification does not disclose a database or computer system comprising data for "at least 20" or "at least 50" nucleic acid sequences (or genes) anywhere.

In the response filed 11/13/06, applicant points to page 3 for support that "at least about 2, 3, 4, 5, 6, 7, 8, 9, 10 or more, or all" the genes in Tables 1-6 may be detected in a sample. Applicant does not point to support for a database comprising (or detection of) "20 or more" or "50 or more" (or at least 20/50) sequences or genes, as now recited in claims 72, 73 and 75. Applicant is again reminded that a new range must have specific support in the same manner that a new species or subgenus must have support, in the originally filed disclosure. Disclosure of a larger range or genus is NOT necessarily supportive of the narrower range or species, as set forth in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90(CCPA 1976). See also MPEP 2163.05, in particular, section III.

As the originally filed disclosure does not provide specific support for the newly recited subset of nucleic acids, claims 72, 73 and 75 recite new matter and are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 59, 61, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58, 59, and 61 recite the term "said nucleic acid molecules," each in line 2, which lacks antecedent basis in the claims. Parent claim 57 recite nucleic acid "sequences," but does not recite nucleic acid "molecules."

Claim 74 recites "expression of SEQ ID NO: 1 to 1124" in line 2. It is unclear whether applicant intends that an expression profile include differential expression of EACH of SEQ ID NO's 1 to 1124, or intends that the profile comprise some subset of the recited range of SEQ ID No's, therefore the claim is indefinite. Clarification through statement in a response or by claim amendment is requested.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest a computer system comprising instructions for identifying the presence or absence of BPH by using differential expression profiles of the nucleic acid sequences recited in the instant claims. While

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the sequences were known in the art, their differential expression profiles were not known to be useful in diagnosing BPH.

For this reason, claims 57, 70 and 71 are allowed and all claims are considered free of the prior art.

Conclusion

Claims 57, 70 and 71 are allowed; claims 58-65 and 72-75 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571)272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
2/20/07